IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

MARIA DALBOTTEN,

Plaintiff,

v.

C. R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.,

Defendants.

Case No. 1:20-cv-00034-SPW

ORDER ON PLAINTIFF'S MOTION IN LIMINE TO EXCLUDE DEFENDANTS' FDA EVIDENCE AND RELATED ARGUMENT

Before the Court is Plaintiff Maria Dalbotten's Motion in Limine to Exclude Defendants' FDA Evidence and Related Argument. (Doc. 230). Plaintiff seeks to exclude any evidence or testimony stating that the FDA (1) has granted 510(k) clearance to market the G2 filter and (2) has not taken any post-clearance enforcement action concerning the G2 filter. (Doc. 230 at 2). Plaintiff argues that the evidence is largely irrelevant and unfairly prejudicial, and accordingly must be excluded under Federal Rules of Evidence 401, 402, and 403. (Doc. 230 at 1). For the following reasons, the Court grants the motion in part and denies the motion in part.

I. Background

A medical device manufacturer can obtain FDA clearance for a new product under a less-rigorous process called 510(k) if the new product is "substantially

equivalent" to a device that has already received pre-market clearance. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); 21 U.S.C. § 360e(b)(1). A device is substantially equivalent if it does not raise different questions of safety and effectiveness than the predicate device. 21 U.S.C. § 360c(i)(1)(A)(ii). The G2 filter received 510(k) clearance in 2005 based on its substantial equivalence to the Recovery filter, which itself received 510(k) clearance in 2002.

II. Legal standards

The Federal Rules of Evidence require that all evidence be relevant to be admissible. Fed. R. Evid. 401, 402. Evidence is relevant if it tends to make a fact at issue more or less likely. Fed. R. Evid. 401. Otherwise relevant evidence may be excluded if its relevance is substantially outweighed by its risk of unfair prejudice, confusing the issues, or misleading the jury, among other considerations. Fed. R. Evid. 403.

Montana imposes a pure statutory strict liability regime on products liability claims. Mont. Code Ann. § 27-1-719. For a products liability claim under Montana law, a plaintiff must prove that the product was in a defective condition and unreasonably dangerous to the user, that the defect caused the injury, and that the defect is traceable to the defendant. *Brown v. North Am. Mfg. Co.*, 576 P.2d 711, 718 (Mont. 1978) (citing Restatement (Second) of Torts § 402A); *see also* Mont. Code Ann. § 27-1-719. Strict products liability may be imposed even if the

seller or manufacturer has exercised all possible care. *Malcolm v. Evenflo Co.*, 217 P.3d 514, 520 (2009). This aspect of Montana's products liability distinguishes it from actions grounded in negligence. *Id.* at 522. Evidence in products liability cases must focus on the condition of the product, rather than the manufacturer's conduct or knowledge. *Id.* at 522-23.

III. Analysis

A. 510(k) evidence

Plaintiff argues that the 510(k) evidence is irrelevant to her products liability claims because it solely relates to Bard's compliance with safety regulations, a topic that the Montana Supreme Court has expressly held is immaterial. (Doc. 231 at 14). Plaintiff also asserts that the 510(k) evidence should be excluded regarding her fraud claims because it is irrelevant and highly likely to confuse the jury regarding the different standards of proof for strict liability and fraud claims. (Doc. 231 at 20).

Defendants respond that the 510(k) evidence is relevant to the products liability claims because it informs the expectations of the implanting physician and because the 510(k) evidence has been included in other sister cases, including the bellwether *Booker* case. (Doc. 254 at 17). Defendants also argue that the 510(k) evidence is relevant as a good faith effort to comply with government regulations

and therefore is conduct inconsistent with the mental state required for punitive damages to attach. (Doc. 254 at 19).

Plaintiff replies that the 510(k) evidence is not properly an effort to comply with regulation, but rather an attempt to skirt full regulation by Bard availing itself of the far more limited and less rigorous 510(k) process, compared with full preclearance. (Doc. 260 at 5-6).

The Court agrees with Plaintiff that the 510(k) evidence is irrelevant to her products liability claims. Montana law is clear, as evidenced in *Malcolm*, that compliance with government regulation or clearance processes is irrelevant to products liability. *See* 217 P.3d at 522. This is unlike *Booker*, where the Court applied Georgia law, which incorporates standards of negligence into products liability claims, including the reasonableness of the manufacturer's conduct. *Booker v. C.R. Bard, Inc.*, 289 F. Supp. 3d 1045, 1049 (D. Ariz. 2018). The same distinction applies as well in the other jurisdictions which permitted the 510(k) documents. The 510(k) approval process is irrelevant under Montana law to whether the product was in a defective condition, unreasonably dangerous to the user, or that the defect caused the injury, and it should accordingly be excluded from consideration regarding Plaintiff's products liability claims.

However, the Court also agrees with Defendants that the 510(k) evidence may be relevant to Plaintiff's fraud claims, including the punitive damages

argument. A jury may award punitive damages when a defendant has acted with actual fraud or actual malice. Mont. Code Ann. § 27-1-221. The defendant's state of mind represents a key element in determining whether a defendant acted with actual fraud or actual malice. *Malcolm*, 217 P.3d at 530. A good faith effort to comply with all government regulations would be evidence of conduct inconsistent with the mental state requisite for punitive damages. *Id.* at 531. This evidence is relevant as to the extent of the fraud, if any, and whether punitive damages are appropriate.

The Court understands Plaintiff's argument regarding whether the 510(k) process represents Bard's desire to comply with government regulations or whether the process constitutes an exemption from a more rigorous process, but that argument goes to weight rather than admissibility. The Court has also considered whether the evidence's relevance is substantially outweighed by its potential for prejudice or likelihood of confusion and concludes that it should not be barred under Rule 403's balancing test. While introduction of the 510(k) evidence regarding one set of claims and barring it for others does pose a danger of misleading or confusing the jury, the evidence is plainly relevant, and the risks do not substantially outweigh this relevance. Furthermore, a curative instruction tailored to this tricky distinction can address those risks. Accordingly, the 510(k)

evidence can be admitted regarding Plaintiff's fraud claims and the appurtenant punitive damages determination.

B. Lack of FDA enforcement action

Plaintiff argues that the lack of FDA enforcement action regarding the G2 filter is irrelevant because the reasons for FDA inaction are purely speculative and lack foundation. Plaintiff further argues that any evidentiary value of the lack of FDA enforcement action is substantially outweighed by the risk of misleading the jury or confusing the issues. The Court agrees. To the extent that a lack of FDA enforcement indicates that Bard did not act fraudulently, it also carries a large risk of confusing and misleading the jury. Even if an expert could opine on the reasons the FDA chooses to enforce or not enforce certain claims, that speculation invites inappropriate comparison between the FDA's decision-making and the duty of the jury to decide the facts based on the law and instructions before them. Accordingly, the motion is granted as to this issue.

IV. Conclusion

Plaintiff's motion (Doc. 230) is GRANTED IN PART and DENIED IN PART.

DATED this 7th day of February, 2023.

Susan P. Watters

SUSAN P. WATTERS
United States District Judge